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| APPLICATION NO.           | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------|-------------|----------------------|---------------------|------------------|
| 10/654,184                | 09/03/2003  | Sven-Erik Carlson    | H60-113 US          | 5172             |
| 21706                     | 7590        | 01/25/2006           | EXAMINER            |                  |
| NOTARO AND MICHALOS       |             |                      | WINAKUR, ERIC FRANK |                  |
| 100 DUTCH HILL ROAD       |             |                      |                     |                  |
| SUITE 110                 |             |                      | ART UNIT            | PAPER NUMBER     |
| ORANGEBURG, NY 10962-2100 |             |                      | 3735                |                  |

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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|                              |                                    |                         |  |
|------------------------------|------------------------------------|-------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b>             | <b>Applicant(s)</b>     |  |
|                              | 10/654,184                         | CARLSON ET AL.          |  |
|                              | <b>Examiner</b><br>Eric F. Winakur | <b>Art Unit</b><br>3735 |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 07 November 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,5-8,10-18 and 22 is/are pending in the application.
  - 4a) Of the above claim(s) 22 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,5-8 and 10-18 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date: _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date: _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7 November 2005 has been entered.

### ***Election/Restrictions***

2. Newly submitted claim 22 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the previously examined claims were directed to an embodiment wherein the increasing means was an amplitude modulating means while newly filed claim 22 is directed to an alternate embodiment wherein the increasing means is at least one filter and baffle.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 22 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Objections***

4. Claims 1 and 5 are objected to because of the following informalities: With regard to claim 1, it appears that the phrase "shifting the wavelength" (line 17) should read "shifting the frequency" to more accurately claim the invention; see for example, specification page 6 or 14 - 17 or claim 10. With regard to claim 5, the term "essential" (line 10) should read "essentially". Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

5. Claims 1, 8, 11 - 16, and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With regard to claim 1, it is unclear how an apparatus can have a light receiver for determining light reflected through a tissue portion (lines 7 - 8) and have the photo detecting element adjacent an opposite side of the tissue from the emitter (lines 15 - 16). With regard to claims 11 - 13, it is unclear whether Applicant intends to claim an additional light source amplitude modulating means or merely to provide a limitation of the element set forth in claim 10. With regard to claim 11, the period in line 2 should be deleted. With regard to claim 14, the phrase "the configuration the tissue portion" is unclear. With regard to claim 15, the phrases "the area", "the one arm end", and "the other arm end" lack antecedent basis. With regard to claim 18, the claim appears to be incomplete as the claim is directed to a method for measuring and/or monitoring but only sets forth a "providing" step; that is, no positively recited steps relate to measuring or monitoring.

***Claim Rejections - 35 USC § 102***

6. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Johnson. Johnson teaches an oximeter that uses frequency division multiplexing to obtain measurement signals for determination of oxygen saturation levels from a subject. Applicant's attention is drawn to Figure 1 and the description thereof.

7. Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Caro. Caro teaches providing a pulsoximetric sensor having one or more LEDs (column 9, lines 43 - 46), a light receiver (112), and beam shaping elements (137, 202, 116, 118) for directing the light from the LEDs, through the beam shaping elements, and into substantially the same location on the tissue.

***Claim Rejections - 35 USC § 103***

8. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson as applied to claim 1 above, and further in view of Isaacson et al. Johnson teaches an oximeter, as described above, but does not teach that the arrangement includes an optical wavelength filter. Isaacson et al. teaches an alternate optical measurement arrangement that includes wavelength filters before a photodetector (column 3, lines 53 - 63) to minimize detection of ambient light while allowing detection of the desired wavelengths. It would have been obvious to one of ordinary skill in the art at the time of the invention to include wavelength filters in the arrangement of Johnson, as taught by Isaacson et al., since this allows reduced interference from detection of ambient light.

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9. Claims 5 - 7, 10 - 14, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson in view of Isaacson et al. for the reasons given in paragraph 8 above.

10. Claims 5 - 8, 10 - 14, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caro in view of Tsuchiya. Caro teaches an oximeter arrangement as described above. Further, Caro teaches that substantially all of the components may be incorporated into the finger clip (column 7, lines 59 - 62) but does not teach that the LEDs are essentially arranged to directly emit to the tissue portion. Tsuchiya teaches alternate equivalent arrangements for illuminating tissue (Figures 13, 14, 15 and the descriptions thereof). It would have been obvious to modify the illumination arrangement of Caro to use essentially direct illumination from the LEDs to the tissue, as taught by Tsuchiya, since it has generally been held to be within the skill level to substitute alternate equivalent expedients.

#### ***Response to Arguments***

11. Applicant's arguments with respect to claims 1, 5 - 7, 10 - 14, and 17 have been considered but are moot in view of the new ground(s) of rejection.

12. With regard to claim 18, Applicant contends that Caro does not teach two LEDs for directing light emitted by the two LEDs directly from the LEDs to substantially a same location on the tissue. However, it is noted that claim 18 additionally includes beam shaping elements between the sources and the subject. As described in paragraph 7 above, Caro teaches such an arrangement.

13. Further, Applicant remarks that the detector of Figure 5 does not involve light from a tissue portion. However, Caro teaches that the detector assembly used to measure the light transmitted through the tissue is essentially the same as that shown in Figure 5 (column 11, line 64 - column 12, line 2). As such, Caro discloses the filter and detectors set forth in the claims.

***Allowable Subject Matter***

14. The following is a statement of reasons for the indication of allowable subject matter: The prior art teaches a variety of optical sensor arrangements, but does not teach or suggest a configuration that includes an LED screwably connected to a clamping mechanism so that the distance between a light receiver and transmitter can be varied while retaining a co-linear beam path there between, in combination with the other claimed elements.

15. Claims 15 and 16 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

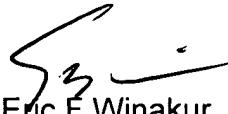
***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric F. Winakur whose telephone number is 571/272-4736. The examiner can normally be reached on M-Th, 7:30-5; alternate Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ali Imam can be reached on 571/272-4737. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Eric F Winakur  
Primary Examiner  
Art Unit 3735

23 January 2006